No. 90-1038

(9)

IN THE

Supreme Court of the United States

OCTOBER TERM, 1990

THOMAS CIPOLLONE, Individually and as Executor of the Estate of Rose D. Cipollone,
Petitioner,

v.

LIGGETT GROUP, INC.,
A Delaware Corporation;

PHILIP MORRIS, INC.,
A Virginia Corporation; and

LOEW'S THEATRES, INC.,
A New York Corporation,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Third Circuit

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BRIEF OF AMERICAN COLLEGE OF CHEST PHYSICIANS AS AMICUS CURIAE IN SUPPORT OF PETITIONER

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BRIEF OF AMERICAN COLLEGE OF CHEST PHYSICIANS AS AMICUS CURIAE IN SUPPORT OF PETITIONER

The American College of Chest Physicians, pursuant to Rule 37 of this Court, submits this brief amicus curiae in support of Petitioner, Thomas Cipollone, Individually and as Executor of the Estate of Rose D. Cipollone, to reverse the judgment of the Court of Appeals for the Third Circuit and remand the case for reconsideration. The American College of Chest Physicians has received the consent of all parties to file this brief as amicus curiae, and letters of consent have been filed concurrently with this brief.

INTEREST OF THE AMICUS CURIAE *

The petitions in this case raise questions of national importance. Couched in legal parlance they involve preemption issues, namely whether the Federal Cigarette Labeling and Advertising Act, 15 U.S.C. §§ 1331-1340 (1982 & Supp. II 1984) ("Labeling Act") constitutes a shield for tobacco companies, absolving them of liability either for failure to provide adequate warnings of the health hazards resulting from smoking or for suppression of health related information and intentional deception of consumers. Given the overwhelming nature of the medical evidence and in particular the powerful addictive aspects of nicotine, we do not believe that the Labeling Act can implicitly preempt state tort claims.

In their briefs, Petitioner and the Amici, the American Cancer Society, *et al.*, analyze the legal aspects of these preemption issues. It is not our purpose to repeat those arguments. We believe, however, that a decision whether the Labeling Act implicitly preempted intentional tort action under state law cannot be divorced from its context of medical evidence both as to the dangers of smoking to health and of the powerful addictive nature of nicotine in tobacco smoke. Issues involving failure to warn, suppression of information, and intentional deception all relate to the widely accepted state of medical evidence and cannot be answered without a recognition of that knowledge. Consequently, this brief will be directed principally toward a review of medical evidence of the adverse health effects of smoking from the early 1920s to the publication of the comprehensive Surgeon General's Report of 1964 [1] and extending through the 1970s and 1980s during which an overwhelming body of medical data accumulated, including the addictive nature of tobacco smoke, and was synthesized in numerous Surgeon General Reports.[2] This overwhelming medical evidence demonstrates that it would be unreasonable to conclude that a statute regulating the size and location of warning labels, and which provided no alternative remedy or relief for persons whose health is adversely affected by tobacco smoke, contained an implicit preemption of remedies available under state law. The fact that the Labeling Act has been amended twice since 1966 without expressly exempting actions under state law, or providing alternative relief, strengthens the conclusion that there can be no implied preemption.

Identity of the Amicus

The American College of Chest Physicians ("ACCP"), founded in 1935 as a medical and scientific society, is dedicated to providing postgraduate medical education for physicians involved in the diagnosis and treatment of

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* Counsel to the American College of Chest Physicians consulted extensively with its President, Alex G. Little, III, M.D., FCCP, Professor and Chairman, Department of Surgery, University of Nevada School of Medicine; its Executive Director, Alfred Soffer, M.D., FCCP, Editor-in-Chief of *Chest* and Professor of Medicine, University of Chicago; Robert S. Fontana, M.D., FCCP, Professor Emeritus of Medicine, Mayo Medical School and Consultant in Internal Medicine, Division of Thoracic Diseases, Mayo Clinic; Douglas R. Gracey, M.D., FCCP, Professor and Vice-Chairman, Department of Medicine, Mayo Clinic; Richard D. Hurt, M.D., FACP, Associate Professor of Medicine, Mayo Medical School, Chair, Division of Community Internal Medicine, Director, Mayo Nicotine Dependence Center; and Thomas E. Kottke, M.D., FACC, Consultant, Associate Professor of Medicine, Mayo Clinic, for their medical expertise and information contained in this amicus curiae brief.

[1] U.S. Dep't of Health and Human Services, *Reducing the Health Consequences of Smoking: 25 Years of Progress—A Report of the Surgeon General* (1989) [hereinafter *1989 Surgeon General's Report*] (citing U.S. Public Health Service, *Smoking and Health: Report of the Advisory Committee to the Surgeon General of the Public Health Service* (1964)).

[2] *See, e.g.*, U.S. Dep't of Health and Human Services, *The Health Consequences of Smoking: Nicotine Addiction—A Report of the Surgeon General* (1988) [hereinafter *1988 Surgeon General's Report*]; *1989 Surgeon General's Report*, *supra* note 1; U.S. Dep't of Health and Human Services, *The Health Benefits of Smoking Cessation—A Report of the Surgeon General* (1990) [hereinafter *1990 Surgeon General's Report*].

chest diseases, including those long-term debilitating cardiopulmonary diseases induced or exacerbated by inhalation of tobacco smoke, *e.g.*, lung cancer, emphysema, coronary artery disease, arteriosclerosis obliterans affecting the lower extremities, bronchitis, and asthma. Requirements for membership in ACCP include certification by an American or Canadian Board, or an international equivalent, as well as certification by one of the subspecialty boards related to cardiopulmonary disease. Additionally, a minimum of eighteen months of training or experience in a chosen subspecialty is required. Fellows of the ACCP must be in good standing in their community and be proposed for membership by other Fellows. Specialties represented by members are pulmonary disease, cardiology, cardiothoracic surgery, critical care medicine, infectious disease, allergy, and related specialties. Approximately 13,000 members practice medicine and surgery in the United States and Canada, and another 1,800 members practice in ninety countries worldwide. Members of the ACCP are professionally involved with the adverse effects of smoking, treating those patients who suffer from heart and lung disease on a daily basis. Every Fellow of the ACCP during the last ten years has pledged to promote the cessation of smoking among his or her patients (see Appendix). This pledge reflects the ACCP's sincere goal to reduce or prevent cardiopulmonary disease.

As physicians, we confront, on a daily basis, debilitating disease and death that result from inhalation of tobacco smoke. With approximately 390,000 deaths annually [3] attributable to the effects of smoking, smoking diseases, such as lung cancer, emphysema, and coronary artery disease, and other cardiopulmonary diseases have become a major social problem of transcending importance.

The concern of the Amicus is magnified by the fact that tobacco smoke contains a powerful addictive drug,

[3] *1990 Surgeon General's Report, supra* note 2, at v.

nicotine. Because of this highly addictive substance, many individuals find it exceptionally difficult to discontinue smoking even when their personal physicians advise them of the dangers to their health, or when they are made aware of printed warning notices on cigarette packages.

Medical science has made giant strides in eliminating some diseases that have afflicted populations in the United States and throughout the world. The ACCP continues to seek new and improved treatments and procedures (including surgery) to ameliorate the effects of diseases resulting from inhalation of tobacco smoke. But, unlike other diseases which medical science has conquered or substantially reduced, elimination or control of smoking diseases may be thwarted by nicotine addiction that renders normal precautionary advice and warnings ineffective.

Although this case raises important questions of federalism and possible preemption of intentional torts arising under state law, the broad medical and social context should not be ignored. The ACCP respectfully urges this Court to consider the medical, historical context and, in particular, the powerful addictive nature of tobacco smoke in its deliberation over the nationally important issues presented by this case.

The opinion of the Court below notes that Rose Cipollone smoked cigarettes, contracted lung cancer as a direct result of her smoking, and subsequently died from lung cancer.[4] Her illness and death occurred during a time in medical history when a great deal of medical evidence concerning the health hazards of smoking became known. We believe that this Court should consider the medical context of Rose Cipollone's death, and in particular, what information was known to the medical profession and increasingly available to the public both prior to and sub-

[4] *Cipollone v. Liggett Group, Inc.*, 893 F.2d 541, 551 (3d Cir. 1991), *cert. granted*, 111 S.Ct. 1386 (1991).

sequent to the effectiveness of the Federal Cigarette Labeling and Advertising Act on January 1, 1966.

To resolve the questions presented it is imperative that the Court take into consideration the volumes of medical data regarding the health hazards of smoking, for without such evidence there would be no preemption issue to decide. More precisely, if little or no medical evidence of the health hazards of smoking had existed, the foundation for actions based upon failure to warn, suppression of information, and intentional deception would have been undermined. Conversely, the pervasive and overwhelming nature of such medical knowledge that did exist lends strong support for such actions under state law. As physicians, we believe that this case involves more than a legal exercise in federalism. The Court should not ignore the real world impact of its decision upon the health of persons throughout the nation.

SUMMARY OF ARGUMENT

Early, reputable scientific studies concerning the adverse health effects of smoking were conducted in the 1920s and 1930s. Medical evidence concerning the physical harms resulting from smoking continued to accumulate, and in 1964 the first Surgeon General's Report stated that the medical community had concluded that smoking has a "causal relationship" to various diseases rather than just a "significant association". Since 1964, medical evidence has steadily expanded to recognize the causal connection between smoking and lung cancer, tongue cancer, lip cancer, cardiovascular disease and chronic obstructive lung disease.[5] In 1986, the Surgeon General reported that non-smokers who inhale secondhand or passive smoke from smokers suffer from the same heart and lung diseases as smokers.[6] By 1988, the

[5] *1989 Surgeon General's Report, supra* note 1, at 5-10.

[6] *1989 Surgeon General's Report, supra* note 1, at 10 (citing U.S. Dep't of Health and Human Services, *The Health Consequences of Involuntary Smoking—A Report of the Surgeon General* (1986a)).

Surgeon General acknowledged what we physicians have known for years: nicotine is addictive. The accumulated medical evidence has not been refuted and cannot be refuted.

The totality of the medical evidence compels the medical conclusion that the warning labels prescribed by the Labeling Act never did and still do not adequately warn the public about the medical realities of smoking.[7] In fact, given the addictive nature of nicotine in cigarettes, the warning labels *per se cannot* adequately warn consumers. A warning label implies the consumer has a choice. A smoking consumer, however, is deprived of any real choice. That person is robbed of choice with the onset of addiction. The preponderance of medical evidence mandates that the Labeling Act cannot implicitly preempt state tort claims.

ARGUMENT

THE DECISION OF THE COURT OF APPEALS SHOULD BE REVERSED ON THE PREEMPTION ISSUES

A. The Early Years: 1920-1957

The medical community, through extensive scientific research and testing, began to recognize the link between tobacco and carcinomas as early as 1920, five years before Rose Cipollone was born. In that year, the Journal of the American Medical Association published scientific survey results of A. C. Broders, linking tobacco use to

[7] We take no position as to whether the Labeling Act should be considered sufficient to preempt state labeling requirements or similar requirements imposed by federal agencies, such as the Federal Trade Commission. We do note, however, that it is apparent that the Labeling Act made no attempt to provide Rose Cipollone, or other similarly situated patients, with any alternative remedy to take the place of the relief she sought under state law. *Saul v. United States*, 928 F.2d 829 (9th Cir. 1991).

lip cancer.[8] Broders' effort was corroborated in 1928, when the New England Journal of Medicine published H. L. Lombard's and C. R. Doering's extensive survey results which found a significant incidence of cancer among heavy smokers.[9] Ten years later, R. Pearl in a study reported in Science, concluded that heavy smokers had a shorter life expectancy than non-smokers.[10] By 1941, one year before Rose Cipollone began smoking at the age of 17, A. Ochsner and M. DeBakey concluded, as reported in the Archives of Surgery, that the epidemic rise of carcinoma of the lung was linked to smoking. The authors concluded:

> It is our definite conviction that the increase in the incidence of pulmonary carcinoma is due largely to the increase in smoking, particularly cigarette smoking, which is universally associated with inhalation.

A. Ochsner & M. DeBakey, *Carcinoma of the Lung*, 42 Archives of Surgery 209, 221 (1941).

In 1950, E. Wynder and E. Graham published their epidemiologic study of 684 cases in the Journal of the American Medical Association, which determined that a strong link existed between tobacco smoke and bronchiogenic carcinoma.[11] By 1954, E. Wynder completed and

[8] *1989 Surgeon General's Report, supra* note 1, at 5 (citing A.C. Broders, *Squamous-cell Epithelioma of the Lip. A Study of Five Hundred and Thirty Seven Cases*, 74 Journal of the American Medical Association 656 (1920)).

[9] *1989 Surgeon General's Report, supra* note 1, at 5 (citing H.L. Lombard & C.R. Doering, *Cancer Studies in Massachusetts. 2. Habits, Characteristics and Environment of Individuals With and Without Cancer*, 198 New England Journal of Medicine 481 (1928)).

[10] *1989 Surgeon General's Report, supra* note 1, at 5 (citing R. Pearl, *Tobacco Smoking and Longevity*, 87 Science 216 (1938)).

[11] *1989 Surgeon General's Report, supra* note 1, at 5 (citing E. Wynder & E. Graham, *Tobacco Smoking as a Possible Etiologic Factor in Bronchiogenic Carcinoma: A Study of 684 Proved Cases*, 143 Journal of the American Medical Association 329 (1950)).

published his own study entitled, "Tobacco As a Cause of Lung Cancer" in which he found definitive proof that tobacco may act as a carcinogen to the human bronchial epithelium, and that a cancer develops in proportion to exposure to a given agent.[12] At the same time Dr. Wynder was publishing his results in 1954, his British colleagues R. Doll and A. B. Hill, were confirming his 1950 conclusions through a prospective mortality study.[13] By 1958, Americans, E. C. Hammond and D. Horn, reconfirmed these earlier results by studying the causes of death of more than 187,000 men over a 44-month period.[14]

The mid to late 1950s proved to be a turning point in our understanding of the relationship between tobacco smoke and cancer. During the 1930s, 1940s, and early 1950s, the medical evidence mounted, as reflected by the above-cited studies, that there was a significant association between tobacco smoke and various cancers—without yet reaching the conclusion that tobacco *causes* cancer. Dr. Wynder's 1954 findings can be viewed as one of the first major steps towards revealing the causal link between inhalation of tobacco smoke and cancer. While

[12] E. Wynder, *Tobacco and Health: A Review of the History and Suggestions for Public Health Policy*, 103 Public Health Reports 8, at 10 (1988) (citing E. Wynder, *Tobacco As a Cause of Lung Cancer: With Special Reference to the Infrequency of Lung Cancer Among Nonsmokers*, 57 Pennsylvania Medical Journal 1073 (1954)). The Surgeon General has recognized that tobacco smoke contains at least 43 known carcinogens. *1989 Surgeon General's Report, supra* note 1, at 12.

[13] *1989 Surgeon General's Report, supra* note 1, at 5 (citing R. Doll & A.B. Hill, *The Mortality of Doctors in Relation to Their Smoking Habits: A Preliminary Report*, 1 British Medical Journal 1451 (1954)).

[14] *1989 Surgeon General's Report, supra* note 1, at 5 (citing E.C. Hammond & D. Horn, *Smoking and Death Rates—Report on Forty-four Months of Follow-up on 187,783 Men. I. Total Mortality*, 166 Journal of the American Medical Association 1159 (1958a)).

the medical research community had clearly linked smoking to cancer by the time Rose Cipollone began smoking in 1942, twelve years passed and Rose Cipollone was well into her nicotine addiction [15] when the causal connection between smoking and cancer was confirmed.

The watershed medical study finding the causal link between smoking and lung cancer was completed by the Study Group on Smoking and Health and was published in June 1957.[16] The Study Group was organized in June 1956 under the sponsorship of the American Cancer Society, the American Heart Association, and the National Cancer and National Heart Institutes at the National Institutes of Health. The distinguished seven-member panel, chaired by Frank M. Strong, University of Wisconsin, Madison, held six 2-day conferences, during which time they examined the most pertinent literature and the most recent unpublished material to determine the effects of tobacco smoking on health and to recommend further needed research.[17]

The Study Group's 1957 Report on the issue of lung cancer states in pertinent part:

> At least 16 independent studies carried on in five countries during the past 18 years have shown that there is a statistical association between smoking and the occurrence of lung cancer . . . . These retrospective studies have been reinforced by two investigations in which large male populations have been followed prospectively. Lung cancer occurs much more frequently (5 to 15 times) among cigarette smokers than among nonsmokers, and there is a direct relationship between the incidence of lung cancer and the amount smoked. It is estimated that on a lifetime basis, one of every ten men who smoke more than two packs a day will die of lung cancer. The comparable risk among nonsmokers is estimated at one out of 275 . . . .
>
> * * * *
>
> The sum total of scientific evidence establishes beyond reasonable doubt that cigarette smoking is a causative factor in the rapidly increasing incidence of human epidermoid carcinoma of the lung.

Study Group on Smoking and Health, *Smoking and Health*, 125 Science 1129 (1957).

[15] The addictive nature of nicotine is discussed below at Part D.

[16] Study Group on Smoking and Health, *Smoking and Health*, 125 Science 1129 (1957).

[17] *Id.*

Despite all of the medical evidence that accumulated during the 1950s, culminating in this 1957 *retrospective* of existing studies, the record below contains evidence of advertising by the tobacco companies during the 1950s that not only failed to alert the public about the dangers of smoking, but asserted that smoking cigarettes was safe and harmless.[18] From a medical perspective, the position of the tobacco industry seems incomprehensible.

While we recognize the fact that the Labeling Act did not go into effect until 1966, truthfulness, fairness, and plain human decency dictate that the tobacco companies should disclose fully all of the medical facts available to smokers as well as to non-smokers exposed to passive smoke. As the Court is aware, the District Court in New Jersey held and the United States Court of Appeals for the Third Circuit affirmed that the tobacco companies failed to warn Rose Cipollone of the harms of smoking prior to the effective date of the Labeling Act.[19]

B. The Great Medical Advance: 1957-1964

Leading up to the release of the Surgeon General's landmark Advisory Committee on Smoking and Health Report in January 1964, there were two significant medical studies completed in Great Britain. Because of the

[18] *Cipollone v. Liggett Group, Inc.*, 893 F.2d at 548-550.

[19] *Id.*

increase in the incidence of chronic diseases around the world, the British (and others) began to look more closely at the relationship between tobacco smoking and disease. In 1957, the British Medical Research Council determined that a significant factor in the rise in lung cancer was attributable to smoking.[20] By 1962, the Royal College of Physicians declared:

> Cigarette smoking is the most likely cause of the recent world-wide increase in deaths from lung cancer . . . is an important predisposing cause of the development of chronic bronchitis . . . probably increases the risk of dying from coronary heart disease . . . has an adverse effect on healing of [gastric and duodenal] ulcers . . . [and] may be a contributing factor in cancer of the mouth, pharynx, oesophagus, and bladder.

1989 Surgeon General's Report, supra note 1, at 6 (quoting Royal College of Physicians, *Smoking and Health: Summary and Report of the Royal College of Physicians of London on Smoking in Relation to Cancer of the Lung and Other Diseases* (1962)).

In the United States, at the urging of the American Cancer Society, the American Public Health Association, the American Heart Association and the National Tuberculosis Association (now known as the American Lung Association), President John F. Kennedy formed the Surgeon General's Advisory Committee on Smoking and Health.[21] The Advisory Committee met nine times between November 1962 and December 1963. During this

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[20] British Medical Research Council, *Tobacco Smoking and Cancer of the Lung. Statement by the Medical Research Council*, 1 British Medical Journal 1523 (1957).

[21] More specifically, the American College of Chest Physicians, along with other select medical and health-related organizations, tobacco industry representatives and Executive Branch representatives consulted with the Surgeon General and assisted in the selection of the distinguished 10-member panel.

time, it reviewed all of the available data from a wide range of studies: over 7,000 studies pertaining to smoking and health, more than 3,000 of which had been published after 1950.[22]

The major conclusion of the Surgeon General's first report in 1964, which set in motion the ultimate passage of the Federal Cigarette Labeling and Advertising Act of 1965, was:

> Cigarette smoking is causally related to lung cancer in men; the magnitude of the effect of cigarette smoking far outweighs all other factors. The data for women, though less extensive, point in the same direction . . . . The risk of developing lung cancer increases with duration of smoking . . . . Cigarette smoking is a health hazard of sufficient importance in the United States to warrant appropriate remedial action.

1989 Surgeon General's Report, supra note 1, at 7 (quoting U.S. Public Health Service, *Smoking and Health: Report of the Advisory Committee to the Surgeon General of the Public Health Service* (1964)).

C. A Survey: Post 1964-Present

Since the Surgeon General's first report was issued in 1964, 20 Surgeon General reports have followed, each one bringing to light new information about tobacco and the health hazards associated with smoking. One year after the Labeling Act went into effect, the Surgeon General's second report, issued in 1967, confirmed and strengthened the 1964 Report, stating, "The case for cigarette smoking as the principal cause of lung cancer is overwhelming . . . . [the evidence] strongly suggests

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[22] *1989 Surgeon General's Report, supra* note 1, at 6 (citing U.S. Public Health Service, *Report of the Advisory Committee to the Surgeon General of the Public Health Service* (1964)).

that cigarette smoking can cause death from coronary heart disease." [23]

The 1968 Surgeon General's Report addressed the loss of life expectancy issue, defining "heavy" smokers as those smoking more than two packs per day and "light" smokers as those smoking less than half a pack per day. Among young men, heavy smokers were estimated to lose 8 years of their lives and light smokers were estimated to lose 4 years of their lives.[24] In 1969, the Surgeon General focused on the health effects of smoking on women. At that time, the Surgeon General was able to confirm an association between maternal smoking and infant low birthweight, as well as an increased incidence of prematurity, spontaneous abortion, stillbirth, and neonatal death.[25]

By 1972, the Surgeon General identified nicotine, carbon monoxide, and tar as constituents most likely to produce health hazards of smoking.[26] And in 1975 the Surgeon General turned his attention to second-hand or passive smoke, noting a linkage of parental smoking to bronchitis and pneumonia in children during their first year of life.[27] With "low tar" and "low nicotine" cigarettes hitting the marketplace, the Surgeon General focused his efforts in 1981 to the "changing cigarette" and concluded that there is no safe cigarette.[28] The 1983 Surgeon General's Report focused on the relationship of smoking and cardiovascular disease, concluding that cigarette smoking is one of three major independent causes of coronary heart disease.[29] The 1984 Surgeon General's Report focused on chronic obstructive lung disease, concluding that smoking is a major cause of that disease, accounting for between 80 and 90 percent of all chronic obstructive lung disease deaths in the United States.[30] As the Court is well aware, the decision below states that Rose Cipollone died in 1984 of lung cancer caused by smoking.[31]

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[23] *1989 Surgeon General's Report, supra* note 1, at 8 (quoting U.S. Public Health Service, *The Health Consequences of Smoking: A Public Health Service Review: 1967* (1968a)).

[24] *1989 Surgeon General's Report, supra* note 1, at 8 (citing U.S. Public Health Service, *The Health Consequences of Smoking: 1968 Supplement to the 1967 Public Health Service Review* (1968b)).

[25] *1989 Surgeon General's Report, supra* note 1, at 8 (citing U.S. Public Health Service, *The Health Consequences of Smoking: 1969 Supplement to the 1967 Public Health Service Review* (1969)).

[26] *1989 Surgeon General's Report, supra* note 1, at 8 (citing U.S. Dep't of Health, Education, and Welfare, *The Health Consequences of Smoking: A Report of the Surgeon General* (1972)).

[27] *1989 Surgeon General's Report, supra* note 1, at 9 (citing U.S. Dep't of Health, Education, and Welfare, *The Health Consequences of Smoking* (1975)).

[28] *1989 Surgeon General's Report, supra* note 1, at 9 (citing U.S. Dep't of Health and Human Services, *The Health Consequences of Smoking: The Changing Cigarette—A Report of the Surgeon General* (1981)).

[29] *1989 Surgeon General's Report, supra* note 1, at 9 (citing U.S. Dep't of Health and Human Services, *The Health Consequences of Smoking: Cardiovascular Disease—A Report of the Surgeon General* (1983)).

[30] *1989 Surgeon General's Report, supra* note 1, at 10 (citing U.S. Dep't of Health and Human Services, *The Health Consequences of Smoking: Chronic Obstructive Lung Disease—A Report of the Surgeon General* (1984)).

[31] *Cipollone*, 893 F.2d at 551.

D. Nicotine is Addictive

The Court below noted that if the jury believes that Liggett's (the cigarette company) pre-1966 conduct proximately caused Mrs. Cipollone to smoke cigarettes and thereby become addicted,

> then those post-1965 cigarettes smoked as a result of the addiction should be considered in discerning whether Liggett's conduct proximately caused Mrs. Cipollone's lung cancer. The Surgeon General has recently concluded that "[s]cientists in the field of

> drug addiction now agree that nicotine, the principal pharmacological agent that is common to all forms of tobacco, is a powerfully addicting drug." U.S. Dep't Health & Human Serv., *The Health Consequences of Smoking: Nicotine Addiction—A Report of the Surgeon General* (1988).

Cipollone v. *Liggett Group, Inc.*, 893 F.2d at 563.

To understand the fact that nicotine is addictive, it is useful first to define the term "addiction". *Dorland's Pocket Medical Dictionary* defines "addiction" as, "physiologic or psychologic dependence on some agent (*e.g.*, alcohol, drug), with a tendency to increase its use." [32] While the Surgeon General's 1988 Report, entitled "Nicotine Addiction," is considered by many experts as the single most authoritative document on the issue, this fact should not be confused with the fact that years ago authoritative medical studies identified nicotine as the active agent in tobacco causing its compulsive use. In 1942, for example, the year Rose Cipollone began smoking, L. M. Johnston equated smoking tobacco as a way to obtain nicotine with smoking opium as a way to obtain morphine.[33] If the analogy seems strained given the illegality of the use of opium, the legal classification should not cloud the medical reality. Pharmacologically, nicotine enters the blood stream rapidly from the lungs and is distributed to the brain, which then affects the central nervous system. More particularly, nicotine acts on specific binding sites or receptors throughout the nervous system, causing electrocortical activity, skeletal muscle relaxation, as well as cardiovascular and endocrine effects, which may act in concert to reinforce tobacco use.[34]

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[32] *Dorland's Pocket Medical Dictionary* 13 (21st ed. 1968).

[33] *1988 Surgeon General's Report, supra* note 2, at 10 (citing L.M. Johnston, *Tobacco Smoking and Nicotine*, 2 Lancet 742 (1942)).

[34] *1988 Surgeon General's Report, supra* note 2, at 13-14.

The legality—or social acceptability—of a drug is not a criterion for determining whether it is addictive in nature. In fact, the Surgeon General's 1988 Report analogizes nicotine to heroin and cocaine, stating in part, "The pharmacologic and behavioral processes that determine tobacco addiction are similar to those that determine addiction to drugs such as heroin and cocaine." [35] Medically speaking, the drug dependence analysis applies equally in both situations. The following criteria, used to determine drug dependence, were summarized by the Surgeon General, who relied on significant input from the World Health Organization, the National Institute on Drug Addiction, and the American Psychiatric Association:

> Primary Criteria of Drug Addiction
>
> - Highly controlled or compulsive use;
> - Psychoactive effects;
> - Drug-reinforced behavior;
>
> Additional Criteria
>
> - Addictive behavior often involves:
>
> —stereotypic patterns of use;
> —use despite harmful effects;
> —relapse following abstinence;
> —recurrent drug cravings;
>
> - Dependence-producing drugs often produce:
>
> —tolerance;
> —physical dependence;
> —pleasant (euphoriant) effects.

1988 Surgeon General's Report, supra note 2, at 7.

A significant amount of medical data demonstrates that smoking cigarettes is not a random exercise that smokers embark upon at their choosing. According to the American Psychiatric Association, it is possible for a smoker to

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[35] *1988 Surgeon General's Report, supra* note 2, at 9.

become nicotine dependent, *i.e.*, addicted to nicotine, if that person smokes continually for at least one month and exhibits at least one of the following diagnostic criteria:

1. serious attempts to stop or significantly reduce the amount of tobacco use on a permanent basis are unsuccessful;
2. attempts to stop smoking lead to the development of Tobacco Withdrawal;
3. the individual continues to use tobacco despite a serious physical disorder, *e.g.*, respiratory or cardiovascular disease, that he or she knows is exacerbated by tobacco use.

American Psychiatric Association, *Diagnostic and Statistical Manual*, 178 (3d ed. 1987).

Tobacco Withdrawal, a medical term of art defined by the American Psychiatric Association, usually occurs within 24 hours of a smoker's abrupt cessation or reduction in tobacco use. Symptoms of Tobacco Withdrawal include craving for tobacco, irritability, anxiety, difficulty concentrating, restlessness, headache, drowsiness, and gastrointestinal problems.[36]

A number of medical studies, dating back to the 1970s demonstrate the addictive nature of smoking by focusing on behavioral patterns. For example, beginning smokers build up their cigarette intake over time until they reach a stable level that remains constant for the remainder of their lives.[37] It has also been documented that an addicted smoker often adopts a pattern of smoking which includes the first cigarette shortly after waking.[38]

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[36] American Psychiatric Association, *Diagnostic and Statistical Manual*, 160 (3d ed. 1987).

[37] *1988 Surgeon General's Report*, *supra* note 2, at 149 (citing L.M. Schuman, *Patterns of Smoking Behavior*, Research on Smoking Behavior, 36 (National Inst. on Drug Addiction Research Monograph 17, 1977)).

[38] *1988 Surgeon General's Report*, *supra* note 2, at 149 (citing K. Fagerström, *Measuring Degree of Physical Dependence to Tobacco Smoking With Reference to Individualization of Treatment*, 3 Addictive Behaviors 235 (1978)).

Many smokers may say they smoke because they enjoy it, not because they are addicted. And many smokers may, in fact, enjoy smoking, because they are addicted! The concepts of enjoyment and addiction are not mutually exclusive. In fact, one of the additional criterion used to determine addiction, as defined by the Surgeon General and cited above, is the drug's ability to produce a pleasant or euphoric effect.[39] Thus it would be consistent for an addicted smoker to "enjoy" a cigarette.

A smoker may overcome his or her addiction, but it takes a recognition that he or she is addicted and a significant amount of perseverance and a program of behavior modification. The fact that 60 to 70 percent of all smokers express a desire to quit, up to 50 percent may try to quit, and approximately only 5 to 7 percent of smokers do not relapse again after a second quit attempt, reveals the severity of nicotine addiction.[40]

These statistics illustrate that the vast majority of smokers simply cannot cease smoking. Smokers who are nicotine dependent, *i.e.*, those who exhibit the diagnostic characteristics enumerated above, can only cease smoking with the proper amount of determination and professional treatment provided by a well-tailored behavior

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[39] *1988 Surgeon General's Report*, *supra* note 2, at 7.

[40] L. Solberg, P. Maxwell, T. Kottke, G. Gepner, M. Brekke, *A Systematic Primary Care Office-Based Smoking Cessation Program*, 30 Journal of Family Practice 647 (1990); *1990 Surgeon General's Report*, *supra* note 2 at 597. Also, see M. Venters, T. Kottke, L. Solberg, M. Brekke, B. Rooney, *Dependency, Social Factors, and the Smoking Cessation Process: The Doctors Helping Smokers Study*, 6 American Journal of Preventive Medicine 185 (1990); and R. Hurt, G. Lauger, K. Offord, T. Kottke, L. Dale, *Nicotine-Replacement Therapy With Use of a Transdermal Nicotine Patch—A Randomized Double-Blind Placebo-Controlled Trial*, 65 Mayo Clinic Proceedings 1529 (1990), both are recent clinical research trials, indicating the severity of nicotine addiction.

modification program geared towards smoking cessation. Such a program must be able to respond to the following medical realities:

1. Chronic tobacco use produces a physical dependence that leads to Tobacco Withdrawal upon the initiation of cessation efforts; and
2. Nicotine intake produces some results which smokers perceive as beneficial, *e.g.*, enhanced performance with respect to certain attention and memory tasks, controlled body weight (due to increased metabolic rate), and reduced stress levels.

1988 Surgeon General's Report, supra note 2, at 468.

There are also a number of environmental factors which must be addressed by a successful modification program:

1. peer pressure
2. family influences
3. tobacco advertising
4. association of smoking with social and work activities.

Id.

Treatment strategies usually fall into one of two categories: pharmacologic or behavioral interventions. Increasingly, treatment strategies involve components of both these interventions. Presently, however, most interventions focus on behavior modification, with the most successful strategies including a combination of approaches such as skills training, group support and self-reward.[41] From a pharmacologic standpoint, nicotine replacement strategies are used to reduce Tobacco Withdrawal and improve the success rate of behavior modification techniques.[42]

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[41] *1988 Surgeon General's Report, supra* note 2, at 465-471.

[42] *Id.* at 469-470.

E. As Physicians We Know

As physicians, we know the great difficulties faced by our patients suffering from nicotine addiction. These difficulties can be measured in part by the number of deaths each year caused by smoking. The Surgeon General's 1990 Report, entitled "The Health Benefits of Smoking Cessation" cites 1985 data which estimates 390,000 Americans die each year from diseases caused by smoking; more than half of these deaths are caused by heart disease and lung cancer.[43] The Surgeon General estimates that of the 390,000 deaths, 99 percent of them occurred in people who began smoking prior to the Surgeon General's 1964 Report.[44]

The Court now has before it the medical evidence concerning the known health hazards of smoking and in particular, the addictive nature of nicotine. This evidence dates back to the 1920s when the first linkages between smoking cigarettes and cancer were discovered, continues through the late 1950s and early 1960s when the first *causal* connections between smoking cigarettes and lung cancer were discovered, reviews the 1970s and 1980s when the addictive properties of nicotine were unmasked and causal links to numerous cancers were reaffirmed and strengthened, and concludes with emphasizing that nicotine addiction is so powerful that most smokers cannot overcome it by themselves. Having the benefit of all of the relevant medical data before it, the Court can now review this medical evidence in conjunction with its review of the relevant statutory language and legislative history to decide whether the Labeling Act implicitly preempts state tort claims and protects tobacco companies if they fail to warn consumers or suppress cigarette-related health information or intentionally deceive consumers about the nature and extent of the health hazards

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[43] *1990 Surgeon General's Report, supra* note 2, at v.

[44] *1989 Surgeon General's Report, supra* note 1, at 22.

of smoking. From a medical vantage point, given all of the medical evidence presented and the powerful addictive properties of nicotine, the Amicus suggest that the Labeling Act *cannot* provide the protection sought.

CONCLUSION

For all of the foregoing reasons, the judgment of the Court of Appeals upholding Respondents' preemption claim should be reversed, and the case remanded for further proceedings.

Respectfully submitted,

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APPENDIX

american college of chest physicians

Pledge

As a Member of American College of Chest Physicians and a leader in the most important struggle faced by chest physicians, the prevention and control of our major health problems of lung cancer, cardiovascular and chronic pulmonary disease, I shall make a special personal effort to control smoking and to eliminate this hazard from my office, clinic and hospital. I shall ask all of my patients about their smoking habits and I shall assist the cigarette smoker in stopping smoking. I make this pledge to my patients and to society.

acp